

**Micro-Pak Enhanced Packaging Sheets:
Enforceable Analytical Method**

DATA REQUIREMENTS:

OPPTS 830.1800

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STUDY COMPLETION DATE:

11/29/12

PERFORMING LABORATORY:

Chemir Analytical Services

LABORATORY TEST IDENTIFICATION:

Sodium Chlorite by XRF

DATA SUBMITTER:

Micro-Pak Ltd.



STATEMENT OF DATA CONFIDENTIALITY CLAIMS

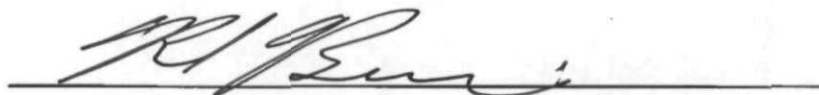
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Company: **Micro-Pak Ltd.**

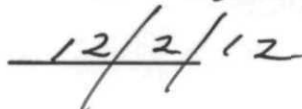
Company Agent: **Robert S. Brennis
Brennis Consulting Services LLC**

Title: **Study Submitter and Agent for
Micro-Pak Ltd.**

Signature:



Date:



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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This report only concerns the development of an enforceable analytical method for this product. There are no Good Laboratory Practice Standards (GLPS) specifically identified for the development of this data. Therefore, the Good Laboratory Practice Standards (GLPS), as specified in 40 CFR Part 160, are not applicable.

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OPPTS GUIDELINE 830.1800

ANALYTICAL METHOD

An analytical method to verify the certified limits for the total amount of Sodium Chlorite in the Enhanced Packaging Sheets is presented below. This method uses X-Ray Fluorescence (XRF) to quantify the amount of chlorine present in Micro-Pak Enhanced Packaging Sheets. The sodium chlorite concentration is then calculated from this determined chlorine value.

Micro-Pak Ltd. Quality Control Procedure

Test Substance Preparation

Sections of the Micro-Pak Enhanced Packaging Sheets are cut and folded over multiple times to create a film stack 12 sheets thick. The stacking is necessary in order to present a sample of "infinite" thickness for the bulk measurement of chlorine in the polymer. A thickness of ~80µm is required.

Method Performance

The measurement area of the method was approximately 30mm by 30mm and was carried out in a vacuum. The sample was prepared three times with each preparation analyzed in triplicate.

This analysis utilized a wavelength dispersive spectrometer (WDXRF) that is capable of detecting elements from atomic number (Z) 4 (beryllium) through atomic number 92 (uranium) at concentrations from the low parts per million (ppm) range up to 100% by weight. The instrument used here was a Rigaku Primus II WDXRF with a rhodium x-ray tube.

Quantification was performed using the Fundamental Parameters (FP) standardless quantification software associated with the system. The fundamental parameters approach uses x-ray physics coupled with established sensitivity factors for pure elements. Data was collected in both scanned and fixed angle modes. In normal scanning mode analysis, the detector is rotated through the full range of dispersion to collect the diffracted x-ray signals coming from the sample and spectra are generated. In a fixed angle analysis the detector dwells at a specific angle for an extended period while collecting a signal only from the peak maximum and from the adjacent background. Fixed angle analysis significantly improves sensitivities. Since a fixed angle analysis collects intensities from only two points (peak maximum and baseline) no spectra are created. The sample was prepared three times with each preparation analyzed in triplicate. From the determined chloride concentration, the amount of sodium chlorite present in the same was calculated using the assumption that all chloride present was in the form of sodium chlorite (see calculation below).

$$\text{Chlorite Conc. in Sample (mass\%)} = \text{Chlorine Conc. (\%)} \times \frac{\text{Sodium Chlorite mass (90.442 g/mol)}}{\text{Chlorine mass (35.45 g/mol)}}$$

Method Performance

The reported values of the analysis of one sample are present in Table 1. The relative standard deviation over all measurements was below 5 % with an average sodium chlorite concentration of 0.143% by mass.

Table 1: Sodium Chlorite concentration replicate analysis

<i>Preparation.</i>	<i>Run</i>	<i>Sodium Chlorite Conc. (%)</i>	<i>Average</i>	<i>%RSD</i>
1	1	0.138	0.138	0.00
1	2	0.138		
1	3	0.138		
2	4	0.140	0.141	1.04
2	5	0.143		
2	6	0.140		
3	7	0.158	0.151	4.48
3	8	0.148		
3	9	0.145		
<i>Average</i>		0.143		
<i>%RSD</i>		4.67		